# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Coverdine 5 mg/1.25 mg/10 mg film-coated tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One film-coated tablet contains 3.395 mg perindopril equivalent to 5 mg perindopril arginine, 1.25 mg indapamide and 13.870 mg amlodipine besilate equivalent to 10mg of amlodipine.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet.

*Product imported from Lithuania:*

White, oblong, film-coated tablet, 10.7 mm long and 5.66 mm wide engraved with  on one face and  on the other face.

## 4 CLINICAL PARTICULARS

As per PA0568/024/003

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0568/024/003

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

*Core:*
Calcium carbonate starch compound: Calcium carbonate 90%, Pregelatinised maize starch 10%
Cellulose microcrystalline (E460),
Croscarmellose sodium (E468),
Magnesium stearate (E572),
Colloidal anhydrous silica,
Pregelatinised starch

*Film-coating:*
Glycerol (E422),
Hypromellose 6mPa.s (E464),
Macrogol 6000,
Magnesium stearate (E572),
Titanium dioxide (E 171)

### 6.2 Incompatibilities

Not applicable.

**6.3 Shelf life**

3 years
For the container of 30 film-coated tablet, the in-use stability after first opening is 30 days.

**6.4 Special precautions for storage**

This medicinal product does not require any special storage conditions.

**6.5 Nature and contents of container**

30 film-coated tablets in polypropylene tablet container equipped with a low density polyethylene flow reducer and a low density polyethylene stopper containing a desiccant.

**6.6 Special precautions for disposal**

No special requirements.

**7 PARALLEL PRODUCT AUTHORISATION HOLDER**

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

**8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA0465/513/002

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 24th January 2025

**10 DATE OF REVISION OF THE TEXT**